REMARKS

This is responsive to the Office Action mailed on October 29, 2003. In that Office Action, the Examiner rejected claims 75-62. With this Amendment, claims 75, 76, 79-81, 83-86, 115-117, 139, 142-145, 153, 161, 183, 205 and 227 are amended, and claims 92-114, 123-138, 140, 141, 149, 157, 162, 163, 171, 179, 184, 185, 193, 201, 206, 207, 215, 223, 228, 229, 237 and 245 are hereby cancelled. The application now includes claims 75-91, 115-122, 139, 142-148, 150-156, 158-161, 164-170, 172-178, 180-183, 186-192, 194-200, 202-205, 208-214, 216-222, 224-227, 230-236, 238-244, and 246-262.

Rejection Under 35 U.S.C. § 112, First Paragraph

In the Office Action, the Examiner rejected claims 75-77, 79, 81, 83-248 under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The Examiner alleged that the above referenced claims contain subject matter which was not described in the specification in such a way to enable one skilled in the art to which it pertains, or with which it is most nearly connected to make and/or use the invention. Specifically, the Examiner stated that "the claims still do not provide 50 grams/day, of which at least 50% passes to abomasums, and the claims are to many alcohols, but only sorbitol is only demonstrated, with sufficient support for xylitol, glycerol, but not the rest."

In response, the claims have been amended to claim in the alternative sorbitol, glycerol, xylitol or any combination thereof or to claim individually sorbitol glycerol or xylitol. It is believed that each and every claim in the application now contains these elements. Therefore the claims, as amended, are not to "many alcohols". In view of these amendments, it is respectfully requested that the rejection under 35 U.S.C. § 112, first paragraph be withdrawn.

Regarding the element of providing 50 grams/day, of which at least 50% passes to the abomasum, it is not understood how not including this element in the claims fails to comply with the enablement requirement. As applicant's attorney understands the enablement requirement, it deals with the issue that the specification does not describe how to make or use the invention in sufficient detail so as to enable one skilled in the art to practice the invention as being claimed. MPEP § 2164.01. This situation typically arises when not sufficient detail is

given in the specification to make or use the claimed invention. This is not the case in the present situation since the element of providing 50 grams/day, of which at least 50% passes to the abomasum, is found on page 10, lines 26-27 and page 11, lines 1 and 2. What it appears that the Examiner is objecting to is that perhaps critical language is not being claimed. This situation is specifically dealt with in MPEP § 2164.08(c). However, no where in the specification does it state that 50 grams/day, of which at least 50% passes to the abomasum is critical. In fact, on page 10, lines 24-26, it is stated:

> "The sugar alcohol, whether feed orally or abomasally to the ruminant, may be fed, in combination with any other feed components, ***at any rate that supplies adequate nutrition***. [emphasis added].

As stated in the MPEP § 2164.08(c) "broad language in a disclosure, including the abstract, omitting an allegedly critical feature, tends to rebut the argument of criticality."

All of the claims provide a rate of supply of the sorbitol, xylitol or glycerol or combinations thereof with the rate being described functionally. For example, independent claim 75 and its respective dependent claims state that the sorbitol, xylitol or glycerol or any combination thereof is provided in an amount that enhances milk component production. Similarly, independent claim 83 and its respective dependent claims state that sorbitol, glycerol, xylitol or any combination thereof are supplied to the abomasum in an amount that supplies a nutritional effect to the ruminant. All of the claims that did not have this type of functional language as to the rate of sorbitol, xylitol or glycerol delivery to the abomasum or to the ruminant have been amended to include such language. All of the claims comply with 35 U.S.C. § 112, first paragraph and the rejection thereunder is requested to be withdrawn.

Rejection Under 35 U.S.C. § 112, Second Paragraph

Next, the Examiner rejected claims 83, 84, 95 and 96 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner stated:

> "It is unclear what patentable weight to give to "significant" of 83, 84 versus "substantial" of 95, 96 in the context of the claim language."

The Examiner's comments are not understood since it appears that the Examiner is comparing the occurrence of the word "significant" in claims 83 and 84 in contrast to the appearance of the word "substantial" in claims 95 and 96. The two sets of claims have no dependency from each, either direct or indirectly. Claims 83 and 95 are separate independent claims and claims 84 and 96 depend from each of these claims respectively. Claims 95 and 96 have been cancelled since these claims became redundant after amending the claims in response to the Examiner's rejection under 35 U.S.C. § 112, first paragraph.

With regard to claim 83 and 84, if the Examiner is objecting to the use of the word "significant" alleging that it is ambiguous, the meaning for the word "significant" is provided for on page 4, lines 28 and 29 of the specification. Therefore, it is believed that the use of word "significant" complies with 35 U.S.C. § 112, second paragraph. It is respectfully requested that the rejection under 35 U.S.C. § 112, second paragraph be withdrawn.

Rejection Under Double Patenting

Next, the Examiner rejected claims 75-262 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 6,440,447. The Examiner alleges that the conflicting claims although not identical, are not patentably distinct from each other and that a timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.32(c) may be used to overcome a rejection under the judicially created doctrine of obviousness-type double patenting. Applicant hereby traverses the Examiner's rejection. First, with regard to the reason for the double patenting rejection, that is, an extension of the "right to exclude", the Examiner's attention is pointed to the fact that the application for U.S. Patent No. 6,440,447 was filed on June 22, 1999. The present application was filed on January 29, 1999. Both patent applications were filed after June 8, 1995 (the date of the enactment of the Uruguay Round Agreements Act), under 35 U.S.C. § 154(a)(2), and the patent terms are therefore calculated 20 years from the filing dates. **The expiration of any resulting patent from this**

application will expire before the expiration of U.S. Patent No. 6,440,447 since this application has an earlier filing date. Therefore, a terminal disclaimer is not necessary, and it is respectfully requested that the rejection under the obviousness-type double patenting be withdrawn.

Rejections Under 35 U.S.C. § 102(b)

Next, the Examiner rejected claims 75, 92-95, 104, 107, 109, 110, 113, 128, 129, 138-141, 153, 157, and 161-163 under 35 U.S.C. § 102(b) as being anticipated by the Baalsrud et al. U.S. Patent No. 3,959,493.

First, claims 92-95, 104, 107, 109, 110, 113, 128, 129, 138, 140, 141, 157, 162 and 163 have been cancelled. Claim 75 does not include the element of a glycerol, but instead is directed to sorbitol. Claim 161 through amendment is now directed to xylitol. Neither claim is anticipated since the Baalsrud et al. patent does not mention either sorbitol or xylitol. In view of this, it is respectfully requested that the rejection under 35 U.S.C. § 102(b) be withdrawn for claims 75 and 161.

The remaining two claims, claims 139 and 153, include glycerol as an element. In both claims 139 and 153, glycerol is ruminally-protected. The Examiner refers to column 5, lines 43-50 of the Baalsrud patent as a disclosure that glycerol is ruminally-protected. Column 5, lines 43-55 contains a discussion of the state of the art by discussing reactions normally taking place in the rumen, that is **unprotected unsaturated fatty acid chains** are **hydrolyzed in the rumen into free fatty acids and glycerol** (column 5, lines 47-48). Further down in column 5, starting on line 63, the invention of U.S. Patent No. 3,959,493 is then discussed. The fatty acids discussed in column 5, lines 43-55 are used as a protective coating and therefore are not protected since such fatty acids are used as a coating to protect medication and diagnostic agents which are administered orally to a ruminant (cow). There is no further mention of glycerol in Baalsrud. Consequently, any glycerol that is released from the protective coating (fatty acid) is therefore not protected in the rumen.

For the Examiner to maintain an anticipatory rejection, the reference must teach every element of the claim. MPEP § 2131. There is absolutely no disclosure in U.S. Patent No.

3,959,493 that glycerol is ruminally protected. In fact, it is unprotected. In view of the above, it is requested that the rejection under 35 U.S.C. § 102(b) based on the Baalsrud et al. U.S. Patent No. 3,959,493 be reconsidered and withdrawn. If the Examiner maintains this rejection, applicant will consider this an appealable issue.

Next, the Examiner rejected claims 75 and 79 under 35 U.S.C. § 102(b) as being anticipated by the Merensalmi U.S. Patent No. 4,127,676.

As far as the rejection of claims 75 and 79 as being anticipated by the Merensalmi U.S. Patent No. 4,127,676, the Examiner is once again directed to the declaration of Paul Porter which demonstrates that the disclosure in the Merensalmi patent is speculative in nature and is contrary to the understanding of others in the art. The Merensalmi data was done *in vitro*. The Examiner's reliance that Merensalmi proves an increase in milk production relies on the fact that **one cow** was used in Example 5. What could be said about Example 5 is that Merensalmi was lucky to have used that cow. One cow does not establish that some how feeding the cow unprotected sugar alcohols resulted in greater milk yield, this is especially so since it flies in the face what is known in the art. Furthermore, the .1 kilogram (3.5 oz.) daily increase of milk in the single cow should be put in perspective. Merensalmi states that a cow yields 30 kg (66lbs) of milk (col. 1, line 26). A .1 kg (3.5 oz.) increase is 0.3%. Such a small increase is statistically insignificant and can be attributed to the single cow's metabolistic fluctuations or the error in weighing the milk. More likely the reason for the increase in milk yield for the single cow is the addition of sodium propionate and propylene glucose which as Merensalmi acknowledged (correctly) are both converted into active glucose in the liver. See Merensalmi, col. 1, lines 66-68.

If read, the Porter declaration contains conclusive evidence that sorbitol does not even reach the duodenum. Therefore, since claim 75 and 79 are limited to sorbitol, the claims are patentable over the cited art of Merensalmi. The fact that the claims are open ended is not relevant since the claims maintain that the sorbitol enhances milk production, however it is transported into the abomasum. Applicant considers this an appealable issue if the Examiner maintains the citation of the Merensalmi patent as an anticipatory reference.

Rejection Under 35 U.S.C. § 103(a)

Next, the Examiner rejected claim 75-77, 79-81, 83, 87-95, 99-114, 128, 129, 133-141, 145, 153, 157, 161-163, 167, 171, 175, 179, 183-185, 189, 193, 197, 201, 205-207, 219, 223, 227-229, 233, 237, 241, 245, 251-255, and 258-262 under 35 U.S.C. § 103(a) as being unpatentable over Khalili et al. 97 and Merensalmi, Makinen et al. 82 and Remond in view of Lister et al. '84 and Cummings et a. 5,585,135 or Baalsrud et al. 3,959,493.

In attempting to establish an obviousness type rejection under 35 U.S.C. § 103(a) the Examiner states as follows:

> "Cummings and Baalsrud (above) provide rumen bypass means, for delivery of drugs and nutrients. The other references are directed at feeding small amounts of sugar alcohols to milking ruminants. Thus, all references would be known by one in the milking production arts."

The Examiner's rejection is not within the guidelines of MPEP § 2143. As MPEP 2143 states "to establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all of the claim limitations.

As MPEP § 2143.01 further states:

> "The mere fact that the references <u>can</u> be combined or modified does not render the resulting combination obvious unless the prior art also suggests desirability of the combination".

The Examiner's statements that "all reference will be known by one in the milking production arts" is insufficient to maintain an obviousness type of rejection.

Regarding the Cummings and the Baalsrud patents as providing "rumen bypass means", there is absolutely no suggestion in what is disclosed in either the Cummings or the Baalsrud patent as providing protection for the passage of sorbitol, xylitol or glycerol past the

rumen and to the abomasum. As discussed previously, the Baalsrud patent at the very most or implies that glycerol is released from the coating in the rumen (the coating being the protection of medications and other nutrients which are to be delivered to the abomasum). There is absolutely no disclosure of the glycerol reaching the abomasum. The glycerol would be unprotected. The Cummings patent discusses the use of glycerol along side a rumen protectable reaction product of fatty acid alkaline earth metal salts and a vegetable protein. The reason for the glycerol, as stated in column 2, lines 63-68, is to improve the palletability of the product for ruminant feeding. Consequently, the glycerol's existence is important to the ruminant's pallet. There is absolutely no disclosure that this glycerol reaches the abomasum since its purpose is for the pallet, and in fact, it is probably eliminated in the rumen. The reaction product of the fatty acid alkaline earth metal salts with vegetable protein needs no protection since this product according to the Cummings patent is inherently non-digestible in the rumen.

More importantly, neither the Cummings nor the Baalsrud patent teach or suggest whatever rumen protection they disclose to be used with either glycerol, sorbitol, or xylitol. The fact that Cummings and Baalsrud in the broad sense disclose a "rumen bypass means" is not relevant to the issue of obviousness in view of applicant's claims.

Regarding the other references such as Khalili, Khalili does not consider rumen protection as is acknowledged by Examiner. It is not understood how Khalili can be combined with Cummings and Baalsrud except only in hindsight, once the applicant's disclosure is considered. The Examiner's statement that

> "Cummings prepared rumen bypass supplements of fatty acids, including stearic, for example (col. 3, lines 32-40) and glycerol (col. 2, lines 52-60)"

is incorrect.

As discussed above, the use of glycerol was not as a protectant nor was there any disclosure of it being protected through the rumen. The glycerol is used to reduce dust to improve palletability. As stated in the Cummings patent, fatty acid salts and denatured protein product (once reacted in the process as discussed in column 2, lines 31-43) has inherent rumen-bypass properties. This product does not have to be protected in the rumen. Cummings intends

this product to be digested in the abomasum and lead to energy source for the ruminant. The items listed in column 4 are suggested to be included along with the fatty acid salts and denatured protein combination but are not said to be rumen protected.

Similarly, Makinen and Remond neither teach nor suggest the use of rumen protection.

The Examiner's remarks that the Makinen article shows increased milk production components on page 1082 is incorrect. The first sentence in the report as to how the polyol groups that were being fed to the cows states:

> "The milk protein concentration did not differ significantly between the test groups (Table V)"

The remainder of the discussion page 1082 involved the differences in enzyme activity within the milk between the different test groups. But enzyme activity is not a milk component. Even if an enzyme were considered a milk component, increased enzyme activity does not mean there is more enzyme. It simply means the activity relating to the enzyme has increased.

The last sentence of the discussion of how the milk was affected in the Makinen article is as follows:

> "The levels of milk glucose (not shown), an inorganic phosphorous (Table V), Na, Ka, Ca, Mg and Fe did not differ significantly between the diet groups."

And finally, the Makinen article on the last page thereof states as follows:

> "The general health and behavior of the polyol-fed cows did not differ from that of the control animals to any significant extent."

The abstract also states that the cows did not differ significantly between the group's protein and glucose.

In view of this, it is not understand how the Examiner can say that the sugar alcohols reached the abomasum since the results in the Makinen article show no significant

difference between the three groups of cows that were studied in terms of protein and glucose of the milk.

Regarding the Remond article, it is not understood how the Examiner can cite this article when it states that milk production was not increased statistically significantly. Therefore, there is no increase in milk production when sorbitol is fed unprotected through the rumen.

The Examiner once again on page 5 mentions the Merensalmi patent, stating that when "molasses, sugar alcohol source, xylitol, arabitol, mannitol, when fed to cows increase milk production." However, this statement is not true. In Example 5, only one lucky cow was fed whose milk production was increased 0.3% (3.5 oz. per day) which is probably well within the error of the weight measurement. Therefore, the results in Merensalmi have absolutely no statistical significance. Furthermore, the Examiner's second statement "Merensalmi attributes increases to passage through the rumen, stating xylitol is less degraded then sorbitol (col. 3, top) is a misreading of this section of Merensalmi. There is absolutely no statement to that effect. Example 1 which the Examiner refers to is an *in vitro* experiment whose results fly in face of evidence to the contrary in the art.

Supporting the fact that *in vitro* experiments do not reflect *in vivo* conditions is the Examiner's next citation, the Lister article. Lister on page 27 the last sentence thereof states:

> "or it may indicate a failure of the *in-vitro* system to reflect precisely the rate of fermentation *in vivo*".

The "*in vitro*" experiment of Lister suggested that no more than 50% of arabinitol or 15% of the xylitol would have disappeared byway of microbial fermentation (rumen activity). However, studies of the actual digesta in the duodenum (portion of the small intestine) showed unexpectedly low amounts of pentitols.

The Examiner's citation and remarks regarding what is shown on pages 26 and 27 of Lister is not understood. The discussion in Lister on page 26 primarily relates to *in vitro* studies, as is clearly indicated, and that the *in vitro* studies did not correlate to the analysis of *in vivo* digesta.

In summary, the Examiner has not established a prima facie case of obviousness under the guidelines of MPEP 2143.01. Reconsideration and allowance of all of the claims is respectfully requested so that an appeal can be avoided.

The Director is authorized to charge any fee deficiency required by this paper or credit any overpayment to Deposit Account No. 23-1123.

Respectfully submitted,

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